



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,268	03/26/2004	Christopher D. Wiegel	7404-600	1636
41577	7590	10/11/2006		
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137				
			EXAMINER TOWA, RENE T	
			ART UNIT 3736	PAPER NUMBER

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/811,268	Applicant(s) WIEGEL, CHRISTOPHER D.	
	Examiner Rene Towa	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to an amendment filed July 21, 2006. Claims 1-9, 11-15 and 17-22 are pending. Claims 10 and 16 have been cancelled. Claims 9 and 14 have been amended. No new claim has been added.

Claim Objections

2. The objection is withdrawn due to amendments.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-2, 4-13, 15-19 and 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Moerman (US Patent No. 6,706,049).

In regards to claim 1, Moerman disclose(s) a bodily fluid sampling device (10, 80), comprising:

an incision forming device 30 to form an incision in a finger; and

an expression cap (16, 85) defining an opening (18, 92) through which the incision forming device 30 forms an incision, the expression cap (16, 85) having an expression surface (22, 88) to express fluid from the incision, the expression surface (22, 88) having at least two opposing compression surfaces (24, 88B) with a negative sigmoidal shape to enhance expression of body fluid from the incision, the expression cap (16, 85) defining a relief notch (26, 87) between the compression surfaces (24, 88B), the relief notch (26, 87) being sized to receive the finger to permit the compression surfaces (24, 88B) to first contact the finger when the expression surface

Art Unit: 3736

(22, 88) is pressed against the finger (see figs. 1, 3B, 4A-B, 10 & 15; column 4/lines 39-42 & 43-48; column 5/lines 16-26, 28-33, 35-38 & 41-44; column 8/lines 32-38 & 54-59; column 8/line 60 to column 9/line 9; column 9/lines 19-28 & 31-36).

In regards to claim 2, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein: the expression cap (16, 85) includes a support portion 12 and an expression portion (14, 81) detachably coupled to the support portion, wherein the expression portion 14 is detachable from the support portion to allow cleaning of the expression portion 14 (see fig. 1; column 4/lines 49-52 & 58-61; column 8/lines 38-45).

In regards to claim 4, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression surface (22, 88) is textured to enhance expression of fluid from the incision (see fig. 3B; column 6/lines 22-36 & 54-58; column 9/lines 31-36).

In regards to claim 5, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression surface (22, 88) defines a plurality of ridges (see fig. 3B).

In regards to claim 6, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the relief notch (26, 87) extends on opposite sides of the opening (18, 92) (see figs. 4A & 10).

In regards to claim 7, Moerman disclose(s) a bodily fluid sampling device (10, 80) further comprising a device body 12 coupled to the expression cap (16, 85) (see figs. 1 & 10).

In regards to claim 8, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression cap (16, 85) is removable from the device body 12 (see fig. 1; column 4/lines 49-52 & 58-61; column 8/lines 38-45).

Art Unit: 3736

In regards to claim 9, Moerman disclose(s) a bodily fluid sampling device (10, 80), comprising:

means for forming an incision 30 in a body part; and

an expression cap (16, 85) defining an opening (18, 92) through which the means for forming the incision forms the incision, the expression cap (16, 85) having an expression surface (22, 88), the expression surface (22, 88) defining a relief notch (26, 87), wherein the expression surface (22, 88) is capable of applying a generally even force against the body part when expressing body fluid from the incision, wherein the expression surface (22, 88) has a negative sigmoid shape (see figs. 1, 3B, 4A-B, 10 & 15; column 4/lines 39-42 & 43-48; column 5/lines 16-26, 28-33, 35-38 & 41-44; column 8/lines 32-38 & 54-59; column 8/line 60 to column 9/line 9; column 9/lines 19-28 & 31-36).

In regards to claim 11, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression surface (22, 88) has a saddle shape (see figs. 4A & 10).

In regards to claim 12, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the relief notch (26, 87) extends across the opening (18, 92) (see figs. 4A & 10).

In regards to claim 13, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression cap (16, 85) has a generally cylindrical shape (see figs. 1 & 10).

In regards to claim 15, Moerman disclose(s) a method, comprising:

Art Unit: 3736

providing a sampling device (10, 80) that has an expression surface (22, 88) with at least two opposing compression surfaces (24, 88B) that have a negative sigmoidal shape and a relief notch (26, 87) defined between the compression surfaces (24, 88B) that is shaped to generally conform to a body part;

placing the expression surface (22, 88) against the body part with at least a portion of the body part received in the relief notch (26, 87);

forming an incision in the body part with the sampling device (10, 80); and
expressing body fluid from the incision by exerting pressure between the body part and the expression surface (22, 88) (see fig. 15; column 7/lines 1-17).

In regards to claim 17, Moerman disclose(s) a method, further comprising analyzing the body fluid with the sampling device (10, 80) (see column 4/lines 39-42).

In regards to claim 18, Moerman discloses a method further comprising keeping the sampling device in place against the body part during said forming and said expressing (see fig. 9; column 10/lines 12-20).

In regards to claim 19, Moerman disclose(s) a method, wherein said placing the expression surface (22, 88) against the body part occurs before said expressing the body fluid (see column 7/lines 1-17).

In regards to claim 21, Moerman disclose(s) a method, wherein said expressing includes pressing the expression surface (22, 88) against the body part (see fig. 9).

In regards to claim 22, Moerman disclose(s) a method, wherein:
the sampling device (10, 80) includes an incision forming device 30;
the expression surface (22, 88) defines an opening (18, 92); and

Art Unit: 3736

said forming the incision includes forming the incision through the opening (18, 92) with the incision forming device (see column 7/lines 1-17).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moerman ('049).

Moerman discloses a sampling device that teaches all the limitations of the claim.

However, Moerman does not expressly disclose that the expression surface is between about 0.2 to 0.6 square inches. Instead Moerman teaches an expression surface area that is capable of receiving a ventral side of a fingertip (see column 8/lines 28-31).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide an expression surface with a surface area between about 0.2 to 0.6 square inches because the Applicant has not disclosed that an expression surface area between about 0.2 to 0.6 square inches provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Moerman's expression surface area and Applicant's invention to have performed equally well with either the dimension suggested by Moerman or the claimed dimension of between

about 0.2 to 0.6 square inches because both dimensions would perform the same function of receiving a fingertip (see column 8/lines 28-31).

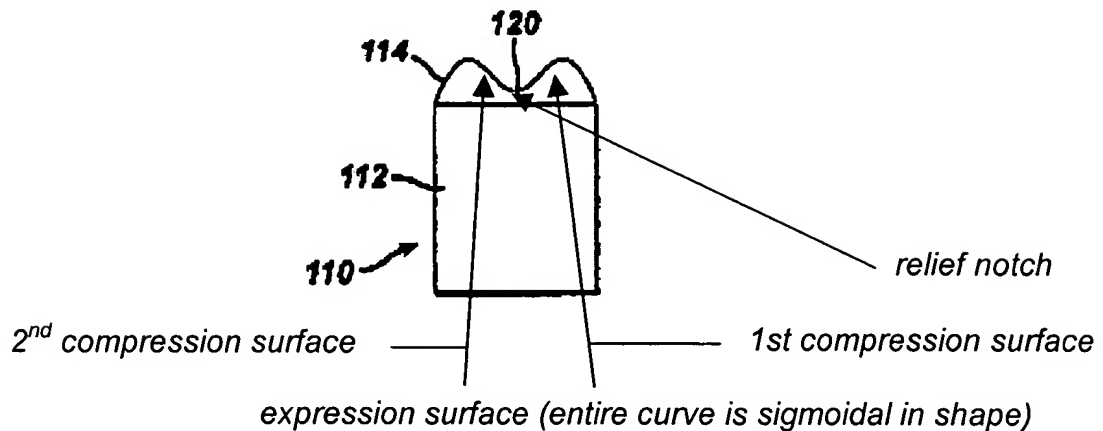
Therefore, it would have been prima facie obvious to modify expression surface area of Moerman to obtain the invention as specified in claim 14 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Moerman.

Response to Arguments

7. Applicant's arguments filed July 21, 2006, with respect to Mitchen (US Patent No. 5,014,718) have been fully considered and are persuasive. The 102 rejection has thus been withdrawn.

8. Applicant's arguments with respect to Moerman have been fully considered but they are not persuasive. Applicant argues that Moerman fails to disclose an expression surface having at least two opposing compression surfaces with a negative sigmoidal shape. This argument has been considered and has not been deemed persuasive.

In regards to Applicant's argument that Moerman fails to disclose an expression surface having at least two opposing compression surfaces with a negative sigmoidal shape, the Examiner respectfully disagrees. As best illustrated in figure 15, Moerman clearly discloses an expression surface having at least two opposing compression surfaces with a negative sigmoidal shape.

FIG. 15

In view of the foregoing, the rejection over Moerman is maintained.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 3736


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758.

The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT


MAX HINDENBURG
PATENT EXAMINER
TECHNOLOGY CENTER 3700